APR 18 2008

K080757

4 510(k) Summary

4.1 Applicant Information

Date Prepared:	April 10, 2008
Submitter:	AGA Medical Corporation
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4.2 Device Information

Trade Name:	AMPLATZER® TorqVue® Low Profile Delivery System
Common Name:	Delivery System
Classification Name:	Catheter, Percutaneous
Classification:	Class II, 21 CFR 870.1250
Product Code:	DQY
Predicate Device:	AMPLATZER® TorqVue® Delivery System 510(k) K072313, Reg. No. 870.1250; Product Code: DQY
	Predicate Device Intended Use: The AMPLATZER® TorqVue® Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.
Device Description:	The AMPLATZER TorqVue Low Profile Delivery System is a sterile, single-use device designed to facilitate the introduction of devices to a location within the peripheral vasculature.

The catheter has a single lumen for passage of transvenous devices with maximum outer diameters of 4 and 5 French. The catheters will be provided in 60 cm and 80 cm usable lengths. The system includes the following components:

- Delivery Catheter – used to deliver transvenous devices
- Loader– used to help introduce the selected implantable device into the delivery catheter
- Delivery Wire (optional) – attaches to the implantable device and facilitates advancement through the catheter, placement and, if desired, recapture of the specified implantable device. [If this surgical accessory (Product Code = DWS) is included, the labeling will specify compatibility with the appropriate implantable devices.]
- Plastic Vise (included with delivery wire) – a handle that is attached to the Delivery Wire by means of a set screw
- Hemostasis Valve– used on the proximal end of the Loader to minimize bleeding from the Delivery Catheter and for flushing air from the system

Intended Use:

The AMPLATZER® TorqVue® Low Profile Delivery System is intended to provide a pathway through which devices are introduced into the peripheral vasculature.

Comparison to Predicate Device:

The AMPLATZER® TorqVue® Low Profile Delivery System is substantially equivalent to the predicate device cleared by K072313. The two systems are both handheld catheter systems designed to facilitate access and placement of specified implantable devices into the peripheral vasculature. Both delivery catheters are single lumen design with a hemostasis valve. The AMPLATZER TorqVue Low Profile Delivery System was created from the existing TorqVue Delivery System and only incorporates modifications to the design and materials that allow for the modified system to be manufactured in a 4 and 5 French size. The modifications have not altered the fundamental scientific technology of the predicate device.

Test Data:

Verification and validation testing confirms that the functional characteristics of the AMPLATZER® TorqVue® Low Profile Delivery Systems are substantially equivalent

to the predicate device cited. This included catheter integrity, catheter kink resistance, leak resistance, hub strength and the ability to deliver various implantable devices.

Summary: Based on the technical information, intended use, laboratory verification tests and *in vitro* performance information provided, the AMPLATZER® TorqVue® Low Profile Delivery System is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2008

AGA Medical Corp.
c/o Mr. Rashmi Bhushan
Senior Regulatory Affairs Specialist
5050 Nathan Lane North
Plymouth, MN 55442-3209

Re: K080757
AMPLATZER TorqVue Profile Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: II
Product Code: DQY
Dated: March 17, 2008
Received: March 18, 2008

Dear Mr. Bhushan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachuer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Statement of Indications for Use

510(k) Number: K080757

Device Name: AMPLATZER® TorqVue® Low Profile Delivery System

Indications for use:

The AMPLATZER® TorqVue® Low Profile Delivery System is indicated to provide a pathway through which devices are introduced into the peripheral vasculature.

Prescription Use ___x___ **OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Jones
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080757